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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,990	09/26/2001	George P. Livi	P51176	3345

7590

01/31/2003

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Corporate Intellectual Property - UW2220

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/31/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/963,990

Applicant(s)

LIVI ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1-25. Claims 1-3 and 12, drawn to a method for producing a transgenic *C. elegans* that expresses at least one human 7TMR pan-neuronally, such that said transgenic *C. elegans* exhibits a known phenotype, a transgenic *C. elegans* produced by the same method, and a method of using the same transgenic *C. elegans* to identify an antagonist of a human 7TMR, classified in classes 800, 800, and 800, subclasses 13, 21, and 3. Each of groups 1-25, corresponds to a transgenic *C. elegans* and a method of making the same, wherein the transgenic *C. elegans* has a phenotype that is one of exploded (Exp), dumpy (Dpy), long body (Lon), hyperactive movement (Hpr), paralyzed (PrI), molt defect (mlt), sterile (Ste), sick (Sck), body morphology defect (Bmd), vuvlaless (Vul), slow growth (Gro), egg laying defect (Egl), larval arrest (Lva), larval lethal (Let), protruding vulva (Pvl), multiple vulva (Muv), sterile progeny (Stp), small (Sma), clear (Clr), blistered (Bli), high incidence of male progeny (Him), roller (Rol), larval lethal (Lvl), uncoordinated (Unc), or embryonic lethal (Emb), respectively.
26. Claim 4, drawn to a method for producing a transgenic *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with behavior, comprising introducing into said *C. elegans* a transgene

encoding a h7TMR in operable linkage to a sensory neuron promoter, classified in class 800, subclass 21.

27. Claim 5, drawn to a method for producing a transgenic *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with behavior, comprising introducing into said *C. elegans* a transgene encoding a h7TMR in operable linkage to a sensory neuron promoter and a different transgene encoding an accessory protein, classified in class 800, subclass 21.
28. Claims 6 and 10, drawn to methods for identifying at least one ligand of at least one human 7TMR, comprising providing at least one *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with behavior, contacting the *C. elegans* with a test substance and detecting modulation of behavior of the *C. elegans*, classified in class 800, subclass 3.
29. Claim 7, drawn to a method of identifying at least one ligand of at least one human 7TMR, comprising providing at least one *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with water-soluble chemorepulsive behavior and detecting the behavior response of at least one *C. elegans* to a chemorepulsant substance, classified in class 800, subclass 3.
30. Claim 8, drawn to a method of identifying at least one ligand of at least one human 7TMR, comprising providing at least one *C. elegans* that

expresses a human 7TMR in the sensory neurons that correlate with water-soluble chemoattractive behavior and detecting the behavior response of at least one *C. elegans* to a chemoattractant substance, classified in class 800, subclass 3.

31. Claim 9, drawn to a method of identifying at least one ligand of at least one human 7TMR, comprising providing at least one *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with behavior, placing at least two different concentrations of at least one test substance on a lawn of bacteria, contacting the at least one *C. elegans* with the lawn of bacteria and detecting a decrease in the density of said uniform lawn of bacteria, classified in class 800, subclass 3.
32. Claim 11, drawn to a method for evaluating the potency of human 7TMR activation by a known ligand, comprising providing at least one *C. elegans* that expresses a human 7TMR in the sensory neurons that correlate with behavior, wherein the 7TMR has a known ligand, contacting the *C. elegans* with the ligand and a structurally related compound, and detecting the behavioral response of the *C. elegans* to the ligand and the structurally related compound, classified in class 800, subclass 3.
- 33-57. Claim 13, drawn to a method for identifying a surrogate ligand present in a strain of transgenic *C. elegans* at least one human 7TMR pan-neuronally, such that said transgenic *C. elegans* exhibits a known phenotype, such that the 7TMR is activated by an endogenous ligand, comprising providing

a strain of transgenic *C. elegans* at least one human 7TMR pan-neuronally, such that said transgenic *C. elegans* exhibits a known phenotype, subjecting the *C. elegans* to at least one mutagenic screen and determining whether the mutagenic screen results in suppression of the known phenotype, classified in class 800, subclass 3. Each of groups 33-57, corresponds to a transgenic *C. elegans*, wherein the transgenic *C. elegans* has a phenotype that is one of exploded (Exp), dumpy (Dpy), long body (Lon), hyperactive movement (Hpr), paralyzed (Pri), molt defect (mlt), sterile (Ste), sick (Sck), body morphology defect (Bmd), vuvlaless (Vul), slow growth (Gro), egg laying defect (Egl), larval arrest (Lva), larval lethal (Let), protruding vulva (Pvl), multiple vulva (Muv), sterile progeny (Stp), small (Sma), clear (Clr), blistered (Bli), high incidence of male progeny (Him), roller (Rol), larval lethal (Lvl), uncoordinated (Unc), or embryonic lethal (Emb), respectively.

58. Claim 14, drawn to a method for identifying at least one substance that agonize the activity of a human 7TMR, comprising providing a strain of transgenic *C. elegans* at least one human 7TMR pan-neuronally, such that said transgenic *C. elegans* does not exhibit a known phenotype because the 7TMR is not activated by an endogenous ligand, contacting the *C. elegans* with a test substance, determining whether the test substance causes a known phenotype in the *C. elegans*, and identifying the test substance resulting in a known phenotype as an agonist of the 7TMR.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups 1-58, because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example, Groups 1-25 are each directed to a different transgenic *C. elegans* having a known phenotype wherein a h7TMR is pan-neuronally expressed, Group 26 is directed to a method of producing a transgenic *C. elegans* that expresses a h7TMR in sensory neurons associated with behavior, Group 27 is directed to a method of producing a transgenic *C. elegans* that expresses a h7TMR in sensory neurons associated with behavior which comprises and expresses an additional heterologous gene that encodes an accessory protein, Groups 28-32 are directed to materially different methods that use a transgenic *C. elegans* that expresses a h7TMR in sensory neurons associated with behavior, Groups 33-57 are directed to methods of identifying ligands using different transgenic *C. elegans* having a known phenotype wherein a h7TMR is pan-neuronally expressed, and Group 58 is directed to a method of identifying an agonist of a h7TMR using a transgenic *C. elegans* that expresses a h7TMR pan-neuronally but does not have a known phenotype. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups 1-58, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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PETER PARAS
PATENT EXAMINER

